



141-287

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
PATENT OPERATION

In re Application of:

Sriwongjanya et al.

Serial No.: **10/617,456**

Group Art Unit: --

Filed: **July 11, 2003**

Examiner: --

For: **FORMULATION AND PROCESS FOR DRUG LOADED CORES**

New York, NY 10036
September 11, 2003

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

The following statement of relevance is submitted with the accompanying
Form PTO/SB/08A.

Document
Designation

Relevance

AA
U.S.P. 4,281,654

Relates to a drug delivery system for controlled ocular therapy.

AB
U.S.P. 4,303,637

Relates to medication indicated for ocular hypertension.

AC
U.S.P. 4,780,318

Relates to an oral pharmaceutical composition.

I hereby certify that this correspondence is being deposited with the
United States Postal Service as first class mail in an envelope
addressed to:

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

on September 11, 2003

Nicholas P. Chiara, Reg. No. 52,737

<u>Document Designation</u>	<u>Relevance</u>
AD U.S.P. 4,792,452	Relates to a controlled release formulation.
AE U.S.P. 4,874,613	Relates to a taste concealing pharmaceutical dosage unit.
AF U.S.P. 4,892,739	Relates to an osmotic continuous dispensing oral delivery system containing a pharmaceutically acceptable active agent having a improved core membrane adhesion properties.
AG U.S.P. 4,911,707	Relates to a monolithic user-activated transdermal therapeutic system.
AH U.S.P. 4,917,676	Relates to user-activated transdermal therapeutic system.
AI U.S.P. 4,927,640	Relates to controlled release beads having glass or silicon dioxide core.
AJ U.S.P. 4,942,040	Relates to a controlled and extended release pharmaceutical preparation and a process for its preparation.
AK U.S.P. 4,952,402	Relates to a controlled release powder and process for its preparation.
AL U.S.P. 4,957,745	Relates to a controlled release pharmaceutical preparation.
AM U.S.P. 4,996,047	Relates to sustained release drug-resin complexes.
AN U.S.P. 5,001,161	Relates to a pharmaceutical composition comprising metoprolol succinate.
AO U.S.P. 5,019,302	Relates to a method for granulation
AP U.S.P. 5,081,154	Relates to metoprolol succinate and a pharmaceutical preparation containing metoprolol succinate.
AQ U.S.P. 5,169,638	Relates to a buoyant controlled release powder formulation.
AR U.S.P. 5,246,714	Relates to a controlled release drug preparation.

AS U.S.P. 5,288,503	Relates to a cryogel oral pharmaceutical composition containing a therapeutic agent.
AT U.S.P. 5,391,377	Relates to a biphasic release formulations for lipophilic acids.
AU U.S.P. 5,399,358	Relates to a sustained release formulations for 24 hour release of metoprolol.
AV U.S.P. 5,399,362	Relates to once-a-day metoprolol oral dosage form.
AW U.S.P. 5,516,531	Relates to a spherical granules having a core coated with a drug and other excipients.
AX U.S.P. 5,518,730	Relates to a biodegradable controlled release flash flow melt-spun delivery system.
AY U.S.P. 5,681,584	Relates to a controlled release drug delivery device.
AZ U.S.P. 5,700,410	Relates to a method of manufacturing wax matrices.
BA U.S.P. 5,707,656	Relates to pharmaceutical formulations containing a pharmacologically active ionizable substance as well as a process for the preparation thereof.
BB U.S.P. 5,785,976	Relates to solid lipid particles, particles of bioactive agents and methods for the manufacture and use thereof.
BC U.S.P. 6,022,562	Relates to medicinal and/or nutritional microcapsules for oral administration.
BD U.S.P. 6,210,712	Relates to a dosage form having first and second coat.
BE U.S.P. 6,284,271	Relates to a multiple unit effervescent dosage form.
BF U.S.P. 6,287,599	Relates to a sustained release pharmaceutical dosage form with minimized pH dependent dissolution profiles.
BG U.S.P. 6,297,240	Relates to a method for treating ophthalmic disease through fast dispersing dosage forms.
BH U.S.P. 6,365,185	Relates to a self-destructing, controlled release peroral drug delivery system.

BI
U.S.P. 6,372,254

Relates to a press coated, pulsatile drug delivery system
suitable for oral administration.

BJ
U.S.P. 6,383,471

Relates to compositions and methods for improved delivery of
ionizable hydrophobic therapeutic agents.

BK
U.S.P. 6,491,950

Relates to a controlled release pharmaceutical composition.

CA
Physician's Desk Reference
55th Edition (2001),
pp. 606-607.

Relates to Toprol XL®.

Full text copies of the prior art are enclosed herewith. It is respectfully
requested that this art be considered by the Examiner in the above-entitled application and
made of record therein.

Pursuant to 37 C.F.R. §1.97 it is believed that no fee is required for
consideration of this Information Disclosure Statement. If a fee is required, the
Commissioner is hereby authorized to charge Deposit Account No. 08-1540.

Respectfully submitted,



Nicholas P. Chiara
Reg. No. 52,737

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English language translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Substitution for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Complete if Known	
		Application Number	10/617,456
		Filing Date	July 11, 2003
		First Named Inventor	Mongkol Sriwongjanya
		Art Unit	
		Examiner Name	
		Attorney Docket Number	141-287
Sheet	2	of	3

U.S. PATENT DOCUMENTS					
Examiner Initials ²	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
	AU	us- 5,399,358	03-21-1995	Baichwal et al.	
	AV	us-5,399,362	03-21-1995	Baichwal et al.	
	AW	us-5,516,531	05-14-1996	Makino et al.	
	AX	us-5,518,730	05-21-1996	Fuisz	
	AY	us-5,681,584	10-28-1997	Savastano et al.	
	AZ	us- 5,700,410	12-23-1997	Nakamichi et al.	
	BA	us- 5,707,656	01-13-1998	Lindstedt et al.	
	BB	us- 5,785,976	07-28-1998	Westesen et al.	
	BC	us- 6,022,562	02-08-2000	Autant et al.	
	BD	us- 6,210,712	04-03-2001	Edgren et al.	
	BE	us- 6,284,271	09-04-2001	Lundberg et al.	
	BF	us-6,287,599	09-11-2001	Burnside et al.	
	BG	us- 6,297,240	10-02-2001	Embleton	
	BH	us-6,365,185	04-02-2002	Ritschel et al.	
	BI	us-6,372,254	04-16-2002	Ting et al.	
	BJ	us- 6,383,471	05-07-2002	Chen et al.	
	BK	us-6,491,950	12-10-2002	Gutierrez-Rocca et al.	
	BL	us-			
	BM	us-			
	BN	us-			

[illegible]

Examiner Signature	Date Considered
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

compliance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449B/PTO

Completion if Known

(use as many sheets as necessary)

Sheet	3	of	3
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Application Number	10/617,456
Filing Date	July 11, 2003
First Named Inventor	Mongkol Sriwongjanya
Group Art Unit	
Examiner Name	
Attorney Docket Number	141-287

Examiner Signature		Date Considered	
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¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

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